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09/485,005	09/11/2000	Erich Wanker	V0179/7001	1379

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EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/485,005	Applicant(s) WANKER ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-12, 18-20 and 27 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 13-17 and 28-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Restriction Election

1. Applicant's amendment and response filed May 25, 2005 is acknowledged and has been entered. Claims 1, 17, and 28-30 have been amended. Claims 31-32 have been added. Accordingly, claims 1-20 and 27-32 are pending and are under examination.

Withdrawn Rejections

2. In light of Applicant's amendment, the rejection of claims 6, 17 and 28-30 under 35 U.S.C. 102(a) as being anticipated by Kalchman et al. (WO 97/18825), is hereby, withdrawn.

3. In light of Applicant's arguments, the rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Kalchman et al. (WO 97/18825) in view of Yanai et al. (US Patent 6,743,432), is hereby, withdrawn.

New Ground of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1641

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-5, 8-12, 18-20, and 27 stand rejected under 35 U.S.C. 102(a) as being anticipated by Kalchman et al. (WO 97/18825) for reasons of record.

Kalchman et al. discussed the role of huntingtin and HIP1 in the pathology of Huntington's disease (HD). Kalchman et al. specifically disclose that the interaction between HD proteins and HIP1 is influenced by the number of polyglutamine repeats and that expanded polyglutamine tracts aggregate into large irregularly shaped deposits in HD brains (see pages 1, 6, and 7). According to Kalchman et al., individuals suffering from Huntington's disease have polyglutamine expansions of at least 35 glutamines, at least 41 glutamines, at least 48 glutamines, or at least 51 glutamines, (36 or greater glutamines) (see page 2). In protein preparation and western blotting for expressions studies, proteins from tissues and cells of human and other mammals were treated with detergent, sodium dodecyl sulphate (separated on SDS-PAGE mini-gels) and HIP1 and huntingtin proteins were captured and detected (transferred and electroblotted) on low protein adsorptivity filter, i.e. PVDF membrane, by Immobilon-P, Millipore.

Immunoreactivity was determined using antibodies against HIP1 and Huntingtin and visualized in chemiluminescent ECL solution. Kalchman et al. further determined that HIP1 colocalized with Huntingtin in P2 and P3 membrane fractions and that solubilization with non-ionic detergent such as t-octylphenoxypolyethoxyethanol, i.e. Triton X-100, revealed that HIP1 is insoluble to Triton X-100 (see Examples 7 and 8).

Response to Arguments

5. Applicant's arguments filed May 25, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that Kalchman et al. does not teach each and every element of amended claim 1, and therefore does not anticipate the claimed invention because amended claim 1 recites "contacting the filter with materials of a sample suspected to include amyloid-like fibrils or protein aggregates which has been previously treated with detergent or urea to solubilize the sample", and "filtering the sample through the filter to capture detergent- or urea- insoluble fibrils and aggregates", and "detecting ...", whereas Kalchman et al. teaches blotting samples from a gel onto a PVDF membrane and does not teach or suggest "filtering a sample through the membrane". Applicant specifically contends that in the Kalchman et al. reference, the proteins are blotted into PVDF membrane - and are not filtered through a filter.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Specifically, claim 1 recites, "contacting the filter with materials of a sample ... which has been previously treated with detergent or urea to solubilize the sample", and "filtering the sample through the filter...", and claim 18 recites that "contacting [step] is effected by dotting, spotting, or pipetting [said] material onto said filter", which is a "filter membrane" (claim 19). As Applicant concurs, the Kalchman et al. reference, indeed, teaches "blotting samples onto a PVDF membrane" (by Immobilon-P, Millipore)

Art Unit: 1641

which in itself is a membrane filter; hence, the recitation of "filtering the sample through the filter" is an inherent teaching by Kalchman et al. Additionally, dictionary definition of the term "blotting" as used by Kalchman is synonymous to Applicant's recitation of the term "dotting" or "spotting" the material of the sample onto the filter in claim 18.

Accordingly, it appears that the teaching of Kalchman et al. reads on claim 1.

B) Applicant argues that the proteins that are blotted onto the PVDF membrane in Kalchman et al. are contained in supernatant obtained from a centrifugation step and electrophoretically separated on SDS- a detergent. Applicant contends that the SDS-PAGE technique in the reference includes solubilizing proteins in SDS detergent; hence, Kalchman fails to teach or suggest the claimed invention.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Specifically, claim 1 is written with a "comprising" transition language; hence, claim 1 does not appear to exclude that the sample material is obtained from a centrifugation step. Additionally, the recitation of "amyloid-like fibrils or protein aggregates ... treated with detergent or urea to solubilize the sample" in claim 1 appears to be consonant with Kalchman et al.'s teaching of electrophoretic separation (treatment) of sample on SDS (detergent) wherein the technique includes solubilizing proteins in SDS detergent, such as recited in claim 20. Accordingly, it appears that the teaching of Kalchman et al. reads on the claimed invention.

Allowable Subject Matter

6. Claims 6, 7, 13-17, and 28-32 are clear of the prior art of record. Claims 6, 7, 13-17 and 28-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach or fairly suggest filtering and capturing detergent- or urea-insoluble amyloid-like fibrils or protein aggregates on low capacity protein adsorption filter and detecting the presence or concentration thereof, wherein the captured amyloid-like fibril or protein aggregate is a fusion protein comprising 1) a polypeptide that enhances solubility or prevents aggregation of the fusion protein; 2) an amyloidogenic polypeptide that self assembles into amyloid-like fibrils or protein aggregates when released from the fusion protein; and 3) a cleavable site that separates 1) and 2) of the fusion protein; and wherein the fusion protein is further incubated with a suspected inhibitor of amyloid-like fibrils and protein aggregate formation, and simultaneously or concurrently, with a compound that induces cleavage at the cleavage site. The object of using low capacity protein adsorption filter is to capture only detergent- and urea- insoluble amyloid-like fibrils and protein aggregates in the filter membrane for detection, and to ensure exclusion of solubilized fibrils and proteins get filtered in solution.

Art Unit: 1641

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
August 8, 2005

grg



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SUPERVISORY PATENT EXAMINER
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08/08/05